

## IN THE CLAIMS

What is claimed is:

1-37. (Canceled)

38. (New) A method of preparing self-tolerance inducing cell of monocytic origin for the prevention, treatment, or prevention and treatment of diseases associated with disturbed self-tolerance in a patient comprising:

- a. isolating a monocyte from the blood of a patient to whom the cells are to be administered;
- b. multiplying said monocyte *in vitro* in a suitable culture medium comprising macrophage-colony stimulating factor (M-CSF);
- c. cultivating said monocytes simultaneously with or following step b) in a culture medium containing gamma-interferon ( $\gamma$ -IFN); and
- d. separating a self-tolerance inducing cell of monocytic origin formed in step c) from said culture medium.

39. (New) The method according to claim 38, wherein said monocyte is from a human.

40. (New) The method according to claim 38, wherein said isolating further comprises a lymphocyte next to said monocyte, wherein said lymphocyte is present in an amount of at least 10% with reference to total cell number in an isolate.

41. (New) The method according to claim 38, wherein said separating further comprises binding said cell to a monoclonal antibody produced by hybridoma GM-7, deposited under DSMZ Accession No. DSM ACC2542.

42. (New) The method according to claim 38, wherein said self-tolerance inducing cell of monocytic origin co-expresses antigens CD3 and CD14.

43. (New) The method according to claim 38, wherein the M-CSF concentration in said culture medium is 1 to 20  $\mu$ g/ml.

44. (New) The method according to claim 38, wherein 3 to 6 days after the beginning of step a) said monocytes are cultivated for 24 to 72 hours in a culture medium containing  $\gamma$ -IFN.

45. (New) The method according to claim 44, wherein said culture medium containing  $\gamma$ -IFN has a  $\gamma$ -IFN concentration of 0.1 to 20 ng/ml.

46. (New) The method according to claim 38, wherein said isolating in step a); said multiplying in step b); and said cultivating in step c) occurs over 4 to 8 days in total.

47. (New) The method according to claim 38, wherein subsequent to step d) said self-tolerance inducing cell of monocytic origin is suspended in a medium selected from the group consisting of a suitable cell culture medium, a PBS solution, and a NaCl solution.

48. (New) The method according to claim 38, wherein said self-tolerance inducing cell of monocytic origin is suspended in a freezing medium and subsequently deep frozen.

49. (New) The method according to claim 48, wherein said freezing medium comprises fetal calf serum (FCS) or human ABO-compatible serum and DMSO.

50. (New) A self-tolerance inducing cell of monocytic origin for the prevention, treatment, or prevention and treatment of diseases associated with disturbed self-tolerance in a patient capable of being obtained by a process comprising:

- a. isolating a monocyte from the blood of a patient to whom the cells are to be administered;
- b. multiplying said monocyte *in vitro* in a suitable culture medium comprising macrophage-colony stimulating factor (M-CSF);
- c. cultivating said monocytes simultaneously with or following step b) in a culture medium containing gamma-interferon ( $\gamma$ -IFN); and
- d. separating a self-tolerance inducing cell of monocytic origin formed in step c)

from said culture medium.

51. (New) The cell according to claim 50, wherein said self-tolerance inducing cell of monocytic origin co-expresses CD3 and CD14 antigens.

52. (New) The cell according to claim 50, wherein said self-tolerance inducing cell of monocytic origin is from a human.

53. (New) A cell preparation comprising a self-tolerance inducing cell of monocytic origin capable of being obtained by a process comprising:

- a. isolating a monocyte from the blood of a patient to whom the cells are to be administered;
- b. multiplying said monocyte *in vitro* in a suitable culture medium comprising macrophage-colony stimulating factor (M-CSF);
- c. cultivating said monocytes simultaneously with or following step b) in a culture medium containing gamma-interferon ( $\gamma$ -IFN); and
- d. separating a self-tolerance inducing cell of monocytic origin formed in step c) from said culture medium; and
- e. suspending said self-tolerance inducing cell of monocytic origin in a suitable medium.

54. (New) A method of preventing, treating, or preventing and treating a disease associated with disturbed self-tolerance in a patient in need thereof comprising administering a pharmaceutically effective amount of a pharmaceutical composition comprising a self-tolerance inducing cell of monocytic origin capable of being obtained by a process comprising:

- a. isolating a monocyte from the blood of a patient to whom the cells are to be administered;
- b. multiplying said monocyte *in vitro* in a suitable culture medium comprising macrophage-colony stimulating factor (M-CSF);
- c. cultivating said monocytes simultaneously with or following step b) in a culture

medium containing gamma-interferon ( $\gamma$ -IFN); and

- d. separating a self-tolerance inducing cell of monocytic origin formed in step c) from said culture medium, wherein said self-tolerance inducing cell of monocytic origin co-expresses antigens CD3 and CD14.

55. (New) A pharmaceutical composition comprising a self-tolerance inducing cell of monocytic origin capable of being obtained by a process comprising:

- a. isolating a monocyte from the blood of a patient to whom the cells are to be administered;
- b. multiplying said monocyte *in vitro* in a suitable culture medium comprising macrophage-colony stimulating factor (M-CSF);
- c. cultivating said monocytes simultaneously with or following step b) in a culture medium containing gamma-interferon ( $\gamma$ -IFN); and
- d. separating a self-tolerance inducing cell of monocytic origin formed in step c) from said culture medium.

56. (New) The pharmaceutical composition according to claim 55 further comprising: step e.) suspending said self-tolerance inducing cell of monocytic origin in a suitable medium.

57. (New) A method of preventing, treating, or preventing and treating an autoimmune disease comprising administering a pharmaceutically effective amount of a pharmaceutical composition according to claim 55 to a patient in need thereof.

58. (New) A method of preventing, treating, or preventing and treating an allergy comprising administering a pharmaceutically effective amount of a pharmaceutical composition according to claim 55 to a patient in need thereof.

59. (New) A method of manufacturing a pharmaceutical composition for the preventing, treating, or preventing and treating of a disease associated with disturbed self-tolerance comprising:

- a. isolating a monocyte from the blood of a patient to whom the cells are to be administered;
- b. multiplying said monocyte *in vitro* in a suitable culture medium comprising macrophage-colony stimulating factor (M-CSF);
- c. cultivating said monocytes simultaneously with or following step b) in a culture medium containing gamma-interferon ( $\gamma$ -IFN); and
- d. separating a self-tolerance inducing cell of monocytic origin formed in step c) from said culture medium.

60. (New) The method according to claim 59, wherein said disease associated with disturbed self-tolerance is an autoimmune disease.

61. (New) The method according to claim 60, wherein said autoimmune disease is one or more of the diseases selected from the group consisting of rheumatic diseases with autoimmune features, diabetes mellitus, autoimmune diseases of the blood and blood vessels, autoimmune diseases of the liver, autoimmune diseases of the thyroid, autoimmune diseases of the central nervous system, and bullous skin diseases.

62. (New) A method of manufacturing a pharmaceutical composition for the preventing, treating, or preventing and treating an allergy comprising:

- a. isolating a monocyte from the blood of a patient to whom the cells are to be administered;
- b. multiplying said monocyte *in vitro* in a suitable culture medium comprising macrophage-colony stimulating factor (M-CSF);
- c. cultivating said monocytes simultaneously with or following step b) in a culture medium containing gamma-interferon ( $\gamma$ -IFN); and
- d. separating a self-tolerance inducing cell of monocytic origin formed in step c) from said culture medium.

63. (New) The method according to claim 62, wherein said allergy is selected from the group

consisting of an allergy induced by non-self proteins, an allergy induced by an organic substance, an allergy induced by an inorganic substance, and combinations thereof.

64. (New) The method according to claim 62, wherein said allergy is a hay fever, an allergy, or a hay fever and an allergy induced by an item selected from the group consisting of a drug, a chemical, a virus, a bacterium, a fungus, a food component, a metal, a gas, a cat skin scale, an animal hair, and a combination thereof.

65. (New) A method of generating, propagating, or generating and propagating autologous regulatory T-lymphocytes *in vitro* comprising utilizing a self-tolerance inducing cell of monocytic origin according to claim 50.

66. (New) The method according to claim 65, wherein said autologous regulatory T-lymphocytes co-express CD4 and CD25 antigens.

67. (New) A method for generating, propagating, or generating and propagating an autologous regulatory T-lymphocytes comprising co-cultivating self-tolerance inducing cells of monocytic origin according to claim 50 with an autologous T-lymphocyte preparation.

68. (New) The method according to claim 67 further comprising obtaining regulatory T-lymphocytes from the culture medium.

69. (New) The method according to claim 68, wherein said regulatory T-lymphocytes co-express CD4 and CD25 antigens.

70. (New) The method according to claim 68, wherein said regulatory T-lymphocytes are obtained from the culture medium by FACS sorting.

71. (New) A method of detecting, selecting, or detecting and selecting a self-tolerance inducing cell of monocytic origin suitable for preventing, treating, or preventing and treating a

disease associated with disturbed self-tolerance in a patient in need thereof comprising adding a monoclonal antibody produced by hybridoma GM-7, deposited under DSMZ Accession No. DSM ACC2542.

72. (New) A method of preventing, treating, or preventing a disease associated with disturbed self-tolerance in a patient in need thereof comprising administering a pharmaceutically effective amount of a self-tolerance inducing cell of monocytic origin according to claim 50 to said patient.

73. (New) The method according to claim 72, wherein said disease associated with disturbed self-tolerance is an autoimmune disease.

74. (New) The method according to claim 73, wherein said autoimmune disease is one or more of the diseases selected from rheumatic diseases with autoimmune features, diabetes mellitus, autoimmune diseases of the blood and blood vessels, autoimmune diseases of the liver, autoimmune diseases of the thyroid, autoimmune diseases of the central nervous system, and bullous skin diseases.

75. (New) The method according to claim 72, wherein said disease associated with disturbed self-tolerance is an allergy.

76. (New) The method according to claim 75, wherein said allergy is selected from the group consisting of an allergy induced by non-self proteins, an allergy induced by an organic substance, an allergy induced by an inorganic substance, and combinations thereof.

77. (New) The method of claim 75, wherein said allergy is a hay fever, an allergy, or a hay fever and an allergy induced by an item selected from the group consisting of a drug, a chemical, a virus, a bacterium, a fungus, a food component, a metal, a gas, an animal skin scale, an animal hair, animal excreta, and combinations thereof.